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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,034	02/09/2004	Stephanie M. Kladakis	022956-0260	6915
21125 7590 05/02/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT 3738		PAPER NUMBER		
NOTIFICATION DATE 05/02/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/775,034

Applicant(s)

KLADAKIS ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30-39 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39 and 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39,42-44,46-50,52,53 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schwartz et al. (2003/78617). Fig. 17 shows a wedge-shaped tissue scaffold. Schwartz et al. disclose the tissue repair device comprises a porous resorbable material, paragraphs 16,17. Schwartz also discloses the material can be synthetic, paragraphs 83,86,94. It can be seen the implant includes top and bottom portions **24,26** respectively. Fig. 34 illustrates the top and bottom portions can be mated to one another. Schwartz discloses the implant pocket material can be an ECM. Schwartz additionally shows (Fig. 23) that there is a tissue material **22** placed in a pocket or hollow interior or lumen that extends from the greater height to the tapered smaller end and is formed between the top and bottom portions. Bioactive substances can be added to the tissue material, paragraphs 130,131. Schwartz et al. disclose that tissue is obtained and comminuted (i.e. mince, slice or sliver) to smaller fragments and then loaded between or within the pocket of the tissue scaffold, paragraphs 16,17,83. Schwartz et al. disclose that osteoblasts are one type of cells placed therein, paragraph 133. Budny (2005/147645) teaches that an ECM provides the necessary framework for cell migration, such as osteoblasts, paragraph 25. Thus, it is inherent that the cells of Schwartz's implantable device migrate into the

scaffold. Figs. 26 and 31 show the implantation is done such that native tissue **12** abuts the opening of the pocket to maintain the tissue **22** therein. Regarding claims 42,43,46-49,52,53 since the ECM **21** covers a portion of the native tissue **12** (Fig. 19) it can be construed that the cells populate a portion of the scaffold and cells from the native tissue populate a portion of the scaffold that lie beneath that portion of the scaffold. With respect to claims 44,50 Schwartz discloses the size of the fragment or tissue can be about 200 μ m, paragraph 122.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 45,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (2003/78617). Schwartz et al. is explained supra. It is noted that Schwartz does disclose that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122. However, Schwartz fails to explicitly disclose the tissue fragments are of a particle size having the dimension of 0.5 mm³ to 3 mm³. It would have been obvious to one of ordinary skill in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells to carry out a process.

Response to Arguments

Applicant's arguments filed 2/12/08 have been fully considered but they are not persuasive. Throughout Applicant's arguments, the focus is on the term "viable". The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) and MPEP 2111.01. It is noted that Applicant uses the term "viable" in the specification, but does not set forth any special definition for the term. Applicants argue that Schwartz does not disclose using "viable" tissue. It is noted that Applicants admit Schwartz disclose using tissue as stated on page 2 of the remarks, but argues it is not "viable". The Examiner would like to point out that the term "viable" means: capable of working. Thus, there is no reason that the tissue of Schwartz cannot be considered to be "viable" tissue or a tissue that is capable of working since it is fully designed to be used for the same purpose as the claimed invention, repairing a tissue defect. Applicant argues that because Schwartz uses ECM tissue, it is not "viable". However, the Examiner is not persuaded since the tissue material clearly performs the same function as claimed and that is having the cells within it to stimulate new cell growth. Applicant additionally argues that the Schwartz disclosure suggests seeding a scaffold with cultured cells that involves isolation and amplification of cells in culture and

thus adds to the cost in preparation of the implant material. The Applicants suggest the time in the claimed invention is thus shortened. However, the fact that appellant has recognized an advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding the comments about the obviousness rejection for the dimensions of the particle size, the Examiner notes that features upon which applicant relies (i.e., certain tissue components are in "viable tissue" that is supposedly not in cultured cells) are not recited in the rejected claim(s). It is also noted that the applicant's argument that Schwartz fails to show certain features of applicant's invention, the tissue fragments are of a particular size has a particular criticality that cannot be found in Schwartz is incorrect. Schwartz can be interpreted to suggest that dimensions can be modified according to the disclosure of Schwartz. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With respect to the article Applicant attempted to argue the criticality of the dimensions, it should be noted that the article was focusing on a function of cells to obtain a desired result. The degree to which something operates is different than whether or not something will function. The Examiner was not stating that the cells would achieve some desired result, but only that their capability to function would not be impeded. The specification provides no basis as to why the fragment size is chosen and appears in the disclosure as some arbitrary selection. Thus, the Examiner's rejection of these claims appears appropriate

in that optimization of dimensions of the tissue material would be within the skill of a scientist.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/
Primary Examiner, Art Unit 3738